Non Technical Abstract (Tab 2)

Background:

Coronary artery disease (CAD) is the leading cause of mortality in the United States. Blocked or narrowed blood vessels in the heart (coronary arteries) cause insufficient blood flow to the heart muscle. Insufficient blood flow for long periods of time causes heart muscle damage. Current coronary artery procedures and drug therapies, including percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG), show significant limitations in treating individuals with large areas of fatty deposits or calcium build up, severe disease in small vessels of the heart or individuals who have already undergone surgical or percutaneous procedures. Although medical and surgical treatments can often provide adequate short-term treatment for individuals with coronary artery disease, an ongoing and increasing need exists to develop other methods of treatment.

The basis of this study is to use therapeutic angiogenesis (a drug used to promote new blood vessel growth and development) as a method to treat or prevent heart muscle damage caused by decreased blood flow. The CI-1023 (investigational drug used in this research study) will be delivered by the Biosense® Intramyocardial Injection Device system. The Biosense® Intramyocardial Injection Device system is inserted through a puncture site at the groin (inner, upper thigh area) and threaded along the inside of the blood vessel pathway into the heart muscle. Once it reaches the interior of the left ventricle (left, lower chamber of the heart), this special delivery system will be used to inject the study drug, CI-1023. Accurate delivery of CI-1023 into the diseased regions of the heart muscle is expected to cause new blood vessel growth within a small area surrounding each point of injection; which in turn, should lead to increased blood flow.

Purpose and Evaluation:

The primary goal of this study is to investigate the tolerability and feasibility of administering CI-1023 using the Biosense® Integrated Intramyocardial Injection Device to patients with long-term, severe angina pectoris (chest pain) and advanced coronary artery disease (CAD) who have no other reasonable and apparent options. This study will enroll 12 patients at up to four (4) clinical sites. The primary time point of evaluation will occur at twelve (12) weeks after the procedure. The same tests and procedures that were performed at the "baseline" time point will be repeated at the "week12" time point for complete comparison evaluation.